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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,648	06/06/2005	Zhi-Cheng Xiao	0380-P03063US 1	6299
110	7590	11/14/2006	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			TSAY, MARSHA M	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/537,648

Applicant(s)

XIAO, ZHI-CHENG

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,7,9-12,15,16 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9-11 and 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,12,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/12/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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Applicant's election with traverse of Group I, claims 2-3, 5, 7, 9-12, 15-16, to SEQ ID NO: 1, in the reply filed on August 28, 2006 is acknowledged. The traversal is on the ground(s) that the inventions listed as Groups I-XIV do not have lack of unity because the claims have corresponding special technical features. Applicants also assert that during the international stage of this application, the Examiner did not make a lack of unity finding and considered all of the claims to be directed to a single invention. This is not found persuasive because as explained in the restriction requirement, the inventions listed as Groups I-XIV do lack unity because the claims do not have a common special technical feature, i.e. peptides with different amino acid sequences. Further, in the International Search Report submitted by Applicants (p. 5), the Examiner did note a lack of unity during the international stage and did find multiple inventions, i.e. directed to peptides with different amino acid sequences, contrary to Applicant's remarks.

The requirement is still deemed proper and is therefore made FINAL.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Claims 1, 4, 6, 8, 13, 14, 17, 28-64 were previously canceled. Claims 2-3, 5, 7, 9-12, 15-16, 18-27 are pending. Claims 18-27 have been withdrawn from further consideration by the Examiner because they are directed to non-elected inventions. Claims 5, 7, 9-11 are also withdrawn because they recite SEQ ID NO: 3. Claims 2-3, 12, 15-16, to SEQ ID NO: 1, are currently under examination.

Priority: The benefit date is December 6, 2002, for the purpose of prior art.

Claim Objections

Claims 3, 12, 16 are objected to because of the following informalities: in claims 3(b) and 12(b), the term “Nog” should be corrected to “Nogo”; in claim 12(c), the term “o” should be corrected to “of”; in claim 16, line 3, the term “stroke” should be followed by “damage” or injury”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 2-3, as written, do not sufficiently distinguish over peptides that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified.” See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 12, 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3, 12, 15 are rejected under 35 U.S.C. 112, first paragraph, because it refers to a peptide only by function.

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. "A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that "in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of

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the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus”.

Here, the instant claims recite a peptide up to 60 amino acids in length comprising the amino acid sequence depicted as SEQ ID NO: 1. From a sequence of 60 amino acids, only seven amino acid residues are known, YLTQPQS (SEQ ID NO: 1). While Applicants have provided functional support for the peptide, there is a lack of sufficient structural information because the remaining residues in the sequence of up to 60 amino acids have not been identified and can be selected from any of the twenty naturally occurring amino acids.

Since said products of claim 12 are inadequately described, a method of use of said products (claim 15) is also inadequately described.

Claims 3, 12, 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods and compositions of SEQ ID NO: 1 to bind to Nogo, MAG, and/or TN-F does not reasonably provide enablement for peptides up to 60 amino acids in length comprising SEQ ID NO: 1 to bind to Nogo, MAG, and/or TN-F. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain which amino acid sequences, up to 60 amino acids in length, comprising SEQ ID NO: 1 will function in the same way as the wild-type peptide. Thus there could be thousands of variants which differ in sequence length and amino acid

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composition. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly which peptides comprising SEQ ID NO: 1 were active.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large since there are combinations to choose from, regarding the length and/or the specific amino acid residue. The amount of guidance in the specification is zero with regard to which and where the amino acids should be positioned as to maintain the binding activity of SEQ ID NO: 1. No working examples are present of fragments and/or differing lengths, up to 60 amino acids in length, and/or

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derivative peptides of SEQ ID NO: 1. The nature of the invention is such that many different peptides that are substantially similar to SEQ ID NO: 1 may or may not have biological activity. The state of the prior art is that even peptides that are 99.99% similar to the wild-type peptide are at times not fully active. The relative level of skill in this art is very high. The predictability as to what substantially similar peptide will have which activity is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 12, 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is drawn to a peptide having an amino acid sequence. The use of the term "having" a sequence is confusing because in chemical practice, "having" the formula means the structural formula and nothing else. However, in common usage, "having" may include or contain other things. Applicant needs to establish what is meant.

Claims 2-3, 12, 15-16 are indefinite because they recite a non-elected SEQ ID NO.

In claims 3, 12, 15-16, the acronyms TN-R, MAG, and CNS should be clearly defined.

In claim 16, line 3, the term "stroke" should be followed by "damage" or injury".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sivakumaran et al. (EMBL Acc. No. Q9BDQ2, Jan. 2001; IDS). Sivakumaran et al. teach a peptide of 13 amino acids comprising at least 6 residues identical with corresponding residues in the amino acid sequence of instant SEQ ID NO: 1 (claims 3, 12).

SEQ ID NO: 1 appears to be free of art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

November 8, 2006

M. Monshipouri
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER